A SUMMARY OF THE NBCCEDP BREAST CANCER SCREENING REIMBURSEMENT POLICIES EXPERT PANEL RECOMMENDATIONS AS PRESENTED IN THE WHITE PAPER ON TECHNOLOGIES FOR THE EARLY DETECTION OF BREAST CANCER

BACKGROUND

An independent expert panel composed of 14 representatives from academia, industry, professional organizations, clinicians, NBCCEDP Program Directors, public health practitioners and other federal agencies was charged with: a) identifying minimum criteria for establishing new reimbursement policies, b) identifying a framework of issues to be considered in policy review, c) providing specific recommendations for reimbursement policies, and d) providing guidance concerning procedures for future reviews of reimbursement policies. Members of the expert panel conferred in subgroups and as a full committee through a series of conference calls and a face-to-face meeting. The following breast cancer screening and detection technologies were reviewed:

- Film mammography (conventional)
- Full field digital mammography
- Computer Aided Detection (CAD)
- Magnetic Resonance Imaging (MRI)
- Ultrasound

REIMBURSEMENT DECISION CRITERIA

Panel members established decision criteria for each technology. Because screening is performed on healthy, asymptomatic women, each new technology must clearly demonstrate its ability to perform equally to or better than current technologies and must meet minimum criteria. That is each new technology must:

- reduce breast cancer morbidity and mortality;
- sustain or enhance the number of program eligible women served by the NBCCEDP;
- sustain or enhance overall quality of care;
- sustain or enhance overall program operations; and/or
- reduce overall health disparities

Beyond these minimum criteria, policies must accommodate differences across programs and remain consistent across programs while still affording flexibility in implementation by local NBCCEDP programs. In addition, as a federal government agency, the CDC must consider related policies established by other federal agencies, in particular the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS).

BASIS FOR TECHNOLOGIES ASSESSMENT

The basis for decisions about whether the NBCCEDP should provide reimbursement for any new technology combines a full range of test characteristics as well as program factors and is unique to each technology. The test characteristics used in this evaluation were accuracy, reproducibility, population characteristics, interval, cost, and NBCCEDP-specific program factors. In addition to test characteristics, public health, patient and clinical factors were taken into consideration.

RECOMMENDATIONS

Following careful review of the test characteristics and public health factors associated with each technology, the NBCCEDP Expert Panel on Breast Cancer Reimbursement Policies discussed potential policies and reached consensus on specific recommendations. An overview of these recommendations and key rationale points for each are presented below.

Digital Mammography

Recommendation: Digital mammography should be reimbursed only at the conventional rate for film mammography. (Recommendation mirrors current policy.)

Rationale: The per-test cost of digital mammography would substantially increase screening costs and reduce the total number of women screened. Currently, there is limited market penetration, insufficient evidence that digital mammography reduces morbidity and mortality, and the lack of standardization limits the overall accuracy of the exam. This recommendation should be reassessed following release of DMIST study findings.

CAD

Recommendation: CAD should not be reimbursed at this time. (Recommendation mirrors current policy.)

Rationale: The costs associated with the addition of CAD to current interpretation procedures and the increase in the number of needed follow-up tests for increased false positive findings based on CAD would substantially increase program costs and reduce the total number of women screened. The added cost of 3 CAD procedures would eliminate program funds for one film mammogram. There is insufficient evidence that CAD would contribute to greater reductions in morbidity/mortality than film mammography. Furthermore, increased rates of false positive findings would result in unnecessary follow-up procedures and anxiety for women.

MRI

Recommendation: MRI should not be reimbursed as a screening examination for either (BRCA 1/2) women at high-risk or average risk for breast cancer at this time. (Recommendation mirrors current policy.)

Rationale: Development and implementation of program systems and procedures to direct MRI screening to a subpopulation of women at high risk and to provide necessary case management and genetic counseling support are overly prohibitive for the relatively small potential public health gain. False positive rates are unacceptably high, resulting in unnecessary tests and anxiety for women. There is a lack of standardization of breast MRI imaging and interpretation limit the overall reproducibility of the exam across settings. In addition, staff time and program resources to implement directed screening could further limit resources. This recommendation should be reassessed following release of ACRIN study findings and formal, clear definition of "high risk."

Ultrasound

Recommendation: Ultrasound should not be reimbursed as a screening examination for either normal or high risk women at this time. Reimbursement should continue for ultrasound as a diagnostic procedure for all women after an abnormal breast examination finding and/or mammogram. (Recommendation mirrors current policy.)

Rationale: False positive rates among women with dense breast tissue are higher, time requirements and increased costs could limit program access, there is also a lack of standardization, and the population most affected would likely be younger women, who have a lower number of cancers than the 50-64 year old NBCCEDP priority population.

Research and Surveillance

In addition to specific reimbursement policy recommendations, the panel developed recommendations to address the general dearth of data to inform policy determinations:

- Fund pilot studies in a subset of NBCCEDP programs to assess current levels of use of CAD.
- Consider pilot assessments of specific reimbursement policy changes on technology practice patterns and the effects of such changes on program operations.

- Initiate planning efforts to more clearly and practically define criteria for high risk.

Future Reimbursement Policy Reviews

The panel recommended that the CDC assess on an annual basis whether new technologies and/or data have emerged that could significantly change existing reimbursement policies. In the presence of new technologies and/or data, an expert panel review of policies should be undertaken. A full policy review should be undertaken at least every 5 years.